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Hip fractures in elderly patients treated with bipolar hemiarthroplasty: comparison between cemented and cementless implants

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Abstract A prospective, randomised study was conducted to evaluate the clinical and functional outcomes at 12 months of follow-up in two groups of patients affected by femoral neck fractures and treated with cemented or cementless bipolar hemiarthroplasty. Fifty-three cemented and 53 cementless prostheses were implanted on alternate days in 106 consecutive patients. We considered general demographic variables (age, sex, side of injury), operative delay, number of pre-existing conditions, ASA score, haemoglobin levels at admission and pre- and postoperatively, number of blood units transfused perioperatively, duration of operation, clinical complications, hospital stay and mortality within one year after discharge. At follow-up, a Total Functional Score (from 0 to 18 points) was used to evaluate walking ability and personal and daily activity. Furthermore, the economic costs of hospital care (medical and nursing staff, drugs, diagnostic procedures, blood transfusions, hospital stay) and prostheses in the 2 groups of patients were considered. There was no significant difference between the 2 groups of patients regarding most variables, except for postoperative haemoglobin value (9.60±1.88 g/dl in cemented group vs 8.80±8.70 g/dl in cementless group, p=0.018) and duration of operation (75.00±22.43 min in cemented group and 56.98±55.00 min in cementless group, p<0.001). Furthermore, there was no difference regarding 1-year mortality (24.5% in cemented group and 26.4% in cementless group) or in total functional score (9.13±6.02 in cemented group and 8.95±5.86 in cementless group). Economic evaluation revealed that the cementless implant costs 1980 euro while the cemented one costs 1065 euro. In our study, the morbility rate for elderly patients with femoral neck fracture was higher than in the literature. The mortality rate and functional outcome at 12 months of follow-up were similar in the two groups of patients. Considering the higher cost for the cementless prosthesis, the use of cementless bipolar hemiarthropalsy does not seem to be justified in daily orthopaedic practice for the treatment of femoral neck fractures in elderly patients.

Key words Femoral neck fracture • Elderly • Bipolar hemiarthroplasty • Costs

Introduction

In 1990, the estimated total number of hip fractures in persons 50 years of age or older was 1 700 000 worldwide; this number is expected to increase to 6 300 000 by 2050 [1]. This increase can be explained primarily by the aging of the population and then on the assumption that no major changes will occur in the health of elderly people or in the treatment or prevention of hip fractures [2].

Recently, attention has been placed on the economic consequences of hip fractures. In the past, in fact, operative treatment for hip fractures was targeted for costs control because of the high cost and the increasing rate at which they were being performed. Earlier studies on the economic costs of hip fractures were limited to the short period of post-operative care [3] and the major element contributing to the cost was the length of hospital stay [4]. So, to reduce the economic impact of surgery, attention was focused on shortening the initial hospital stay [5, 6]. Nevertheless, an early transfer of sugically treated patients to a rehabilitation department did not reduce the total cost of management of hip fractures in elderly patients [7, 8].

Regarding treatment, hemiarthroplasty using devices such as the Moore and Thompson endoprosthesis has been used in femoral neck fractures for at least 40 years, but a high rate of complications (e.g. loosening, dislocation, acetabular erosion) has been reported [9]. New prosthetic designs, in particular the bipolar endoprosthesis, and new methods of cement fixation have improved the results of hemiarthroplasty, but its use is still a matter of debate.

To investigate the importance of any changes or improvements in surgical technique over time, we considered mortality, morbidity, and clinical and functional outcomes at the 12-month follow-up in 2 groups of patients with femoral neck fractures treated with cemented or cementless bipolar hemiarthoplasty. We also considered the economic costs of treatment, including the costs of the prosthesis and of hospital stay.

Materials and methods

This prospective study covers 106 consecutive patients treated surgically in our department for femoral neck fractures from 1 September 2000 to 31 December 2001. The patients were treated on alternate days with two different implants: 53 patients received cemented bipolar hemiarthroplasty (cemented group) and 53 received cementless bipolar hemiarthroplasty (cementless group).

Patients were at least 65 years old with no upper age limit. Patients with age <65 years old, with fractures secondary to malignant tumors, but with life expectancy more than 3 months, were included in the study. Patients with pathological origins of the fracture with life expectancy inferior to 3 months (treated with internal fixation by screws) were excluded from the study.

The general status of each patient's health was defined by the number of pre-existing major medical conditions which included diabetes mellitus, congestive heart failure, cardiac arrhythmia, ischemic heart disease, cerebrovascular accident, renal disease, cancer, Parkinson's disease, hypertension, chronic obstructive pulmonary disease and anticoagulation therapy. These conditions were chosen on the basis of our experience and as reported in literature [10, 11]. According to Zuckerman et al. [12], who reported that patients with no or only one pre-existing medical condition had similar outcomes with respect to mortality, we also categorised our patients in one of three categories: no or one pre-existing medical condition, two pre-existing medical conditions, and at least three pre-existing medical conditions.

To assess the role of severity of the patient's health problems at the time of admission, the classification system of American Society of Anesthesiologists (ASA) was used. According to this system, grade I indicates a normal healthy patient; grade II a patient who has mild systemic disease, grade III a patient who has severe but not incapacitating systemic disease, grade IV a patient who has a severe, incapacitating systemic condition that is a constant threat to life, and grade V a patient who is near death.

The timing of the operation was based on factors such as the patient's health status, the surgeon's preference and the availability of the operating room. The interval between admission and operation was measured as the difference in calendar days between the date of operation and that of admission. For example, a patient who was admitted to the hospital on Sunday and had the operation on Wednesday was considered to have an interval of three days.

Before surgery, we considered the haemoglobin level of patients at admission and the value measured early in the morning of the operation day. Three patients needed pre-operative blood transfusion with 2 units of concentrated red cells (2 patients in the cemented group and 1 in cementless group) because they had a haemoglobin level less than 8.5 g/dl.

Until surgery, we applied skin traction with a 2-kg weight in all patients.

Rachianaesthesia was performed in all patients. For the surgical procedure, we used a lateral approach according to Bauer in supine position. In the cemented group, a cemented endoprosthesis with bipolar head was implanted, while in cementless group we used a cementless endoprosthesis with bipolar head. The size of the prosthesis was decided using a template to measure the femoral canal and the femoral head diameter. Surgical time was considered from "skin to skin", i.e. from the skin incision to the complete suture of the wound.

All patients were allowed full weight-bearing on the third day after operation, when possible, and on the basis of the general medical conditions of patient.

Postoperative haemoglobin level was taken as the lowest level reported in the first 48 post-operative hours. A blood transfusion with 2 units of concentrated red cells was given to every patient with haemoglobin less than 8.5 g/dl.

Postoperative complications were distinguished into general and local. General complications included myocardial infarction, cardiac arrhythmia, pneumonia, pulmonary embolism, thrombophlebitis, decubitus, urinary tract infection and gastric disease. Local complications included deep wound infection, prosthesis dislocation and iatrogenic femoral fracture. Minor complications such as electrolyte imbalance were not included.

Follow-up

A radiographic control of the operated femur was performed the day after the surgical procedure and six months after hospital discharge. At the 1-year follow-up, information on each patient's vital status was obtained by telephone interview. We also investigated mortality during the hospital stay and within 1 year after discharge from hospital.

For patient's vital status evaluation, we took into consideration the total functional score, described in a study named Verona Elderly Care (VELCA), recently used in Verona, Italy. VELCA is a one-year prospective study carried out between 1997 and 1998 and published in 2001, to analyse the costs of hospitalisation from admission to discharge of patients, in elderly persons with common geriatric pathologies, including proximal femoral fractures. The total functional score takes into account 4 questions regarding the patient: walking ability, personal activities, daily activities and living conditions of the patient after discharge. The questions were scored from 0 to 4 or 6 points for a total possible score of 18 points (Table 1). Walking capacity is the ability of the patient to walk with or without a cane or crutch at home or outdoors. Personal daily function is the ability of a patient to eat, to perform personal care and hygiene, and to dress by himself. Daily home function is the capacity of a patient to perform easy domestic activities, to cook simple foods, to wash dishes and to use public services. Institutionalisation refers to the condition of the patient: living in an institute, at home alone or at home with other persons. The mortality rate was considered at the 1-year follow-up.

Table 1 Total functional score developed in the Verona Elderly Care (VELCA) study [24]. The highest score is 18 and the lowest is 1

Function	Score
Walking ability	
Alone outdoors without cane	6
Alone outdoors with cane	5
Alone outdoors with crutches	4
Alone at home without cane	3
Alone at home with cane	2
Alone at home with crutches	1
Unable to walk	0
Personal activities	
Independent	4
Low dependency	3
Medium dependency	2
High dependency	1
Total dependency	0
Daily activities	
Independent	4
Low dependency	3
Medium dependency	2
High dependency	1
Total dependency	0
Living conditions	
Alone at home	4
Independent with family	3
Dependent with family	2
Istitute	1

Costs

The most reliable method to determine the true financial impact of hip fracture treatment is to assess the cost of all single procedures during the hospital stay, comparing the two different group of patients. We did not consider the additional costs of treatment after hospital discharge, which have been assessed in 3 other studies [2, 13, 14].

So, to analyse the costs of hospitalisation, as reported in VELCA, we considered the cost of a standard number of services of medical and nursing staff, including the cost of the operating room, as reported by the Economic Office of our hospital. We considered the cost of one hour of work of a medical doctor and a nurse, and the mean of estimated numbers of assistance hours necessary for treatment. The same evaluation was made for the costs of diagnostic and instrumental equipment, drug therapy and blood transfusions.

Regarding the costs of surgical material, we considered the difference between the two types of bipolar endoprostheses implanted. For bipolar cemented endoprostheses, we summed the costs of the stem, femoral head, cement and distal plug for femur. For the cementless implant, we considered the costs of the stem and femoral head with its components (Table 4).

Statistical analyis

Statistical analysis was performed using SPSS 11.5 software package. Differences in the means of continuous data were analysed with Student's t test for independent samples. Mann-Whitney test was used when data had no normal distribution. The unadjusted chi-square test was used to compare proportions. A difference was considered statistically significant if $p< 0.05$.

The sample size and allocation ratio that we chose gave at least an 80% chance of showing a 3-point difference in the total function score (1 year) at the 5% significance level.

Results

A total of 106 elderly patients with femoral neck fractures were alternatively treated with cemented or cementless bipolar hemiarthroplasty. The patients were predominantly women in the 2 groups and there was no significant difference regarding most of the considered parameters, such as gender, age, side of injured leg and number of pre-existing comorbidities (Table 2).

The hip fractures had all been provoked by low-energy trauma such as falls from standing position, falls from a chair or other trivial trauma. At the moment of trauma, most patients were at home (43 in cemented group and 39 in cementless group), some were living in institutes for the elderly (5 in cemented group and 10 in cementless group), some were taking a walk outdoors (3 in cemented group and 3 in cementless group) and the remainder were in other hospital departments (2 in cemented group and 1 in cementless group). Furthermore, the social environment of the patients was as follows: most lived alone (19 in cemented group and 20 in cementless group), some lived with relatives (27 in cemented group and 22 in cementless group) and others lived in geriatric institutes or in hospital (7 in cemented group and 11 in cementless group); there was no significant difference between the two groups regarding social environment.

The average ASA score for disease severity was 2.56 in cemented group and 2.55 in cementless group. Surgery was

Table 2 Clinical characteristics of 106 consecutive patients treated for femoral neck fractures, by type of bipolar hemiarthroplasty, before surgery, in the immediate postoperative period and, for VELCA scores and mortality, at the 1-year follow-up

	Cemented group (n=53)	Cementless group (n=53)	*p* value
Age, years[a]	82.09 (7.60)	79.68 (8.62)	NS
Female, n (%)	4 (75.5)	42 (79.2)	NS
Right hip operated, n (%)	29 (54.7)	31 (58.5)	NS
Operative delay, days[a]	2.67 (1.40)	2.72 (1.26)	NS
Pre-existing conditions, n (%)			
0–1	26 (49.1)	27 (50.9)	
2	16 (30.2)	10 (18.9)	NS
3–4	11 (20.7)	16 (30.2)	
ASA score, mean (median)			
ASA class, n (%)	2.56 (3)	2.55 (3)	
ASA 1	4 (7.5)	2 (3.8)	
ASA 2	18 (34.0)	24 (45.3)	NS
ASA 3	29 (54.7)	23 (43.4)	
ASA 4	2 (3.8)	4 (7.5)	
Haemoglobin, g/dl[a]			
Admission	12.94 (2.01)	12.45 (1.62)	NS
Morning before surgery	11.76 (1.81)	10.76 (1.31)	
Lowest value in 48 h after surgery	9.60 (1.88)	8.80 (8.70)	0.018
Number of blood units transfused[a]	1.69 (2.01)	1.64 (2.00)	NS
Surgical time, min[a]	75.00 (22.43)	56.98 (55.00)	<0.001
Hospital stay, days[a]	71.23 (9.10)	17.46 (6.29)	NS
Patients with ≥1 complications, n (%)	16 (30.2)	22 (41.5)	NS
VELCA functional scores[a]			
Walking ability	2.75 (2.30)	3.03 (2.22)	NS
Personal activities	2.28 (1.45)	2.21 (1.42)	NS
Daily activities	1.73 (1.75)	1.42 (1.69)	NS
Living conditions	2.38 (6.02)	2.29 (1.01)	NS
Total functional score	9.13 (6.02	8.95 (5.86)	NS
Mortality at 1 year, n (%)	13 (24.5)	14 (26.4)	NS

ASA, American Society of Anesthesiology's classification of severity of a patient's health; *NS*, not significant; *VELCA*, Verona Elderly Care Study

[a] Values are mean (SD)

performed on average 2.67 days after admission in cemented group and 2.72 days in cementless group (Table 2). Before operation, 3 patients needed blood transfusions (2 in the cemented group and 1 in cementless group); there was no significant difference in pre-operative haemoglobin level between the 2 group of patients. The duration of surgery was different in the 2 group of patients ($p<0.001$) because cementation of the femoral stem required more time. In our experience, a cemented implant needs about 18 additional minutes with respect to a cementless implant (75.00 min vs. 56.98 min). The postoperative haemoglobin level was significantly different between the 2 groups of patients ($p=0.018$), but there was no difference in number of blood transfusions. The average time spent in hospital was 17.23 days in cemented group and 17.46 in cementless group (not significant).

Postoperative complications were distinguished into general and local. There was at least 1 complication in 16 patients in the cemented group and in 22 patients in the cementless group (Table 2). In Table 3 we present the number of local and general complications in the 2 groups of patients, because some patients reported more than 1 complication.

After discharge, most patients were transferred to geriatric institutes (29 in cemented group and 28 in cementless group). Some patients returned home (13 in cemented group and 18 in cementless group) and a few patients were transferred to other medical departments (8 in cemented group and 5 in cementless group). Finally, 3 patients in cemented group and 2 patients in cementless group died during the hospital stay in the orthopaedics department before discharge.

At the 6-month radiographic control, there was no incidence of bipolar head migration in the pelvic bones, stem subsidence or osteolysis in either group.

At the 1-year follow-up, the social environment of the patients was as follow: 26 patients in cemented group and 24 in cementless group lived with relatives, 7 in cemented group and 6 in cementless group lived alone, and 12 in cemented group and 10 in cementless group were institutionalised. The other 10 patients in cemented group and 12 patients in cementless group died between hospital discharge and the 1-year follow-up.

Mortality rates 1 year after operation were similar in the 2 groups. Respiratory infection was the most common cause of death, followed by cerebrovascular accident, congestive cardiac failure, carcinomatosis, septicaemia, pulmonary embolism and chronic renal failure.

The mean total costs for treatment in the two groups of patients were different as result of the costs for the prosthesis (Table 4). In fact, the cementless implant is

Table 3 Local and general complications, by study group. Values are numbers of patients

	Cemented group	Cementless group
Local complications		
Deep wound infections	1	0
Prosthesis dislocations	1	0
Iatrogenic femur fractures	0	2
General complications		
Arrhythmia/myocardial infarction	4	2
Pneumonia/pulmonary embolism	4	3
Urinary tract infection	8	9
Gastric disease	1	1
Decubitus	2	4

Table 4 Costs of hospital care for bipolar hemiarthroplasty in elderly patients, and differences between cemented and cementless approaches. Values are means for 53 patients in each group, and are expressed in euros

	Cemented group	Cementless group	Difference
Medical staff	315	315	0
Nursing staff	757	757	0
Drugs	170	170	0
Diagnostic procedures	298	298	0
Prostheses	1065	1980	915
Hospital stay	351	351	0
Blood transfusion	137	137	0
Total	3093	4008	915

more expensive than the cemented one. In our Department, the cost for the cemented endoprosthesis is as follows: 402 euro for the stem, 453 euro for the femoral head with its components and 213 euro for the cement with the femoral plug (total, 1065 euro); the cost for a cementless implant is 1523 euro for the stem and 456 euro for the femoral head with its components (total, 1980 euro).

Discussion

This study was performed in elderly patients, with femoral neck fractures, to assess the effects of cemented or cementless bipolar hemiarthroplasty on patients' vital function and on mortality rate at the 1-year follow-up. While other investigators have specifically assessed the impact of one operative technique on mortality, our study expands this issue by comparing two different surgical approaches to hemiarthroplasty.

The first consideration regards the pre-operative parameters, in which there were no significant differences between the 2 groups of patients. To estimate the importance of pre-existing comorbidities, we considered the studies of Zuckerman et al. [12], who reported 65% of patients with 0 or 1 pre-existing medical conditions, 23% of patients with 2 condition and 12% of patients with 3 or more conditions. In our study, overall 50.0% of patients had 0 or 1 pre-existing condition, 24.5% had 2 conditions and 25.5% had 3 or more conditions. It is notable that the percentage of patients with 3 or more pre-existing medical conditions is twice as high in our study. We are not able to explain this important difference between our study and those of Zuckerman et al. [12], especially since the mean ages of patients were similar.

Regarding the operative delay, Zuckerman et al. [12] found no association between the prevalence of complications and operative delay. In fact, 6% of patients who did not have an operative delay and 5% of patients who did have a delay had a major complication. Nevertheless, a delay of 3 or more calendar days from admission to operation almost doubled the risk of mortality within the first year after fracture, and this association was not conditional on the number or severity of the medical conditions. Our findings seems to be in conflict with those of Kenzora et al. [15], which is cited frequently in the literature. These authors reported that an operative delay was associated with decreased mortality: 28% mortality rate for healthy patients who had had the operation within one day after admission and 4% mortality rate for those who had had the surgical procedure on the second to fifth day after admission [15].

Considering unprotected weight-bearing soon after implantation of cementless hip prosthesis, it had been thought that increased micromotion of the stem could result in fibrous fixation at the implant-bone interface [16]. More recently, others reported satisfactory clinical and radiographic results in patients who were allowed full weight-bearing immediately after surgery with total hip replacement [16]. Furthermore, full weight-bearing after surgery shortened the rehabilitation process and the hospital stay, in the absence of radiographic migration of the prosthesis or clinical complications [17].

Postoperatively, we found a significant difference between groups for surgical time and haemoglobin values. The cemented implant required a median surgical time 18 minutes more than the cementless implant (75.00 minutes in cemented group and 56.98 minutes in cementless group). In the literature, the average duration of surgery for cemented implants is 73.5 minutes and the cement setting takes approximately 10 minutes [18]. Our cementing technique involves a meticulous cleaning of the femoral marrow cavity and the use of cement plastic extruder without pressurization of the cement. We believe that the surgical technique does not demand an excessive amount of time and, if done by an experienced surgeon, this time could be reduced to 10 minutes. During cementation of the femur, none of our patients suffered cardiac or respiratory diseases, as has been reported in other works [19, 20].

The average haemoglobin level measured after the surgical procedure was higher in the cemented group than the cementless group. In fact, we believe that the cement setting in the femoral cavity during an endoprosthesis implant reduces the blood loss from bone because the cement crowds every blood vessel of the marrow. So, we can say that a cementless endoprosthesis bleeds more than a cemented implant. Nevertheless, the numbers of blood units transfused were similar in the 2 groups of patients and, at the moment, we are not able to correlate these two findings. Furthermore, looking at the haemoglobin level at admission and pre- and postoperatively, we observed a low variance (SD) in the two groups of patients, except for the postoperative measurement in the cementless group; we are not able to explain this unpredictable result.

The two most important parameters to evaluate the results of the 2 techniques are the mortality rate and the functional activity of patients at 1 year of follow-up. An age of 85 years or more, male sex, the presence of 2 or more pre-existing medical conditions and an American Society of Anesthesiologists (ASA) grade of III or IV are significant predictors of mortality [12]. Mortality within 1 year after the fracture varies between 19% [14] and 36% [21], and our results (24.5% in cemented group and 26.4% in cementless group) do not differ from these sta-

tistics. We considered the mortality at 1 year because after this time the life expectancy of elderly patients with hip fractures begins to equal that of the general population of the same age [22]. Nevertheless, in a recent work, the mortality rate 24 months after surgery increased until 41.4% [18].

As regards the functional results of surviving patients 1 year after surgery, there was no significant difference in the 2 groups of patients. Nevertheless, in accordance with the literature, these functional results are far from being optimum because 50% of patients lost their ability to perform simple activities with compromising their independence in daily life. These patients often became dependent on third-party assistance and they were confined to geriatric institutions.

With the Total Functional Score, the standard deviation of the total score for the 2 groups of patients is higher than the mean total score. In fact, most patients had a high or low total score. In other words, at 1 year of follow-up, there were 2 patterns of patients, independent of the treatment they received: patients with high total score with good general conditions and high level of daily activity, and patients with low total score with poor general condition and poor level of daily activity.

There is no doubt that surgery is the best treatment for femoral neck fractures. We observed no difference in clinical outcome comparing the cemented and cementless bipolar hemiarthroplasties.

As regards the costs of care during the initial hospitalisation, they are varied among different countries. The mean cost for elderly patients with hip fracture is about $ 7000 in Europe, with the lowest cost reported for Norway ($ 739) and the highest for Switzerland ($ 44 000) [2]. In Belgium, two different studies reported costs of $ 9534 and $ 8977, and in a study from the United States, the cost was $ 11 480 [2].

Parker et al. [23] reported in 1992 the cost of hip fractures in England, by summing the components of treatment such as the operation, rehabilitation, and other clinical treatments, including revision surgery, within one year of injury; the cost was evaluated in 3293 pounds. Nevertheless a comparison of the costs reported in those countries is hampered by differences in study design, failure to adjust for exchange rates and variations in clinical care and case mix.

So, even if there is no difference in clinical results comparing cemented and cementless bipolar hemiarthroplasty, there is an important difference in costs of treatment, because the bipolar cementless endoprosthesis is more expensive. All other treatments, such as medical and nursing staff, drugs, instrumental diagnoses and blood transfusions, have similar costs. So, we believe that it is reasonable to implant the most economic prosthesis, that is to say the cemented one (1065 euro vs. 1980 euro).

Our study confirms that the economic burden associated with hip fracture is substantial, and highlights the need for strategies to prevent this type of fracture. Such strategies are urgently required, given the fact that, in industrialised Western countries, the number of hip fractures in elderly patients is expected to at least double by the year 2040 [14]. Obviously, appropriate methods for controlling the costs of hip fractures will have to be developed, but these reductions in costs must be achieved without lowering the standards of patient care. As it is the responsibility of the surgeon to ensure that each patient receives state-of-the-art care during the hospital stay, it remains of utmost importance that the management staff of health care catalyse every future effort to reduce the need for institutionalisation of patients after discharge.

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